

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed April 24, 2008. Claims 1-22 were pending, claims 4 and 11 were withdrawn, and claims 1-3, 5-10, and 12-22 were rejected in view of cited art.<sup>1</sup> Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

### **B. PRIOR ART REJECTIONS**

#### **I. REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejected claims 1, 2, 3, 5, 9-10 and 14-22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,674,231 (*Green*) in view of U.S. Patent No. 6,517,569 (*Mikus*). Claims 7-8 and 12-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Mikus* and applied to claim 1, and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Mikus*, as applied to claim 1 and further in view of U.S. Patent No. 5,868,755 (*Kanner*). Applicant respectfully traverses the Examiner's rejections for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims. By contrast to the presently claimed invention, *Green*,

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<sup>1</sup> Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

*Mikus*, *Martinez*, and *Kanner* neither teach nor suggest the apparatus and method claimed in pending claims 1-3, and 5-22.

The Examiner acknowledges that *Green* neither teaches nor suggests “a skin, or sleeve member, overlying at least a portion of the out surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member” (Office Action, Page 3). For such, the Office Action cites *Mikus*. “The clinician may begin the initial deployment of stent 50” following positioning of the catheter (Col. 5, ll. 16-17). “[R]estrainers 56 [are removed] from the proximal extension of peel-away sheath 20” and the “clinician then displaces the outer sheath 15 proximally” (Col. 5, ll. 24-25). “Because outer sheath 15 is rigid, stent 50 can only so expand within the now-exposed portion of peel-away sheath 20”, i.e., the distal portion of the sheath, resulting in the stent forcing “the exposed portion of [the distal portion of the] peel-away sheath 20 to separate along its longitudinal slits” (Col. 5, ll. 30-35). With this separation, the distal end of the peel-away sheath then “resembles two flower petals” (Col. 5, line 38).

Rather than separating from the distal end toward the proximal end, independent claim 1, recites, in part, “advancing the carrier assembly towards the distal end of the elongate member, the carrier assembly causing the skin to separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin as the carrier assembly is advanced towards the distal end” (emphasis added). This is the reverse of *Mikus*. Similarly, independent claims 17 and 20 recite, in part, “advancing the carrier assembly towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted from a proximal end of the sleeve member toward the distal end of the sleeve member to permit such advancement” and “advancing the carrier assembly towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded from a proximal end of the sleeve member toward the distal end of the sleeve member to permit such advancement” (emphasis added). *Green*, *Martinez*, and *Kanner* do not overcome this deficiency of *Mikus*.

In addition to the above, Applicant respectfully submits that there would be no reason to add the sleeve of *Mikus* to the disclosure of *Green*. The device of *Green* includes a surgical clip “releaseably supported on a distal end portion of elongated body 20” (Col. 5, ll. 30-32). This

elongated body “is introduced into the interior lumen 102 of blood vessel 104 through a conventional cannula 100 which had previously been extended through the hole 106 in the wall of the blood vessel” (Col. 7, ll. 19-22). When the clip is to be deployed, the “cannula 100 is withdrawn in a proximal direction with respect to the elongated body 20” (Col. 7, ll. 39-40). There would be no reason to modify the teaching of *Green* with the sleeve of *Mikus* because *Green* already includes a sleeve or sheath to protect the delivery device. Adding a sleeve would protect a clip that is already protected by the sleeve or sheath. In contrast, the invention of independent claims 1, 17, and 20 includes a sleeve member to protect the clip during distal delivery and deployment.

In view of the failure of *Green*, *Mikus*, *Martinez*, and *Kanner* to teach the apparatus and methods claimed in independent claims 1, 17, and 20, Applicants submit that the Examiner has failed to set forth a *prima facie* case for obviousness and respectfully request that the rejection be withdrawn.

### C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds and remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 25<sup>th</sup> day of August, 2008.

Respectfully submitted,

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